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Organizational impact of governmental audit of blood transfusion services in Norway: A qualitative study

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ABSTRACT

Little is known about the organizational impact of supervisory activities in blood banks. We did a study with the aim to explore health professional's experiences with the external audit of blood transfusion services in Norway. The audit and supervision brought attention to deficiencies in systems and practices, and had been a catalyst for quality improvement. We identify facilitators and barriers to change. While audits can bring attention to known deficiencies, and trigger improvement processes which previously have not been prioritized, involvement of senior management is important to secure change across departments.

1. Introduction

Specialized health services in Norway, including most hospitals and transfusion services, are organized in health enterprises owned by the state [1]. The regulatory framework for transfusion services in Norway is developed by the Ministry of Health and Care Services, in accordance with Directive 2002/98 EC of the European Parliament and of the Council [2]. The Directorate of Health and the Norwegian Knowledge Centre for the Health Services develop the specific standards for the national system of hemovigilance [3]. The governmental supervisory authority is divided between the Norwegian Medicines Authority, focusing on blood as a product, and the Norwegian Board of Health Supervision (NHBS), focusing on the transfusion service as health care provision. NHBS has two main approaches for maintaining its supervisory duties. The first is to perform planned audits of services provided, mainly by performing system audits, and if necessary imposing corrective measures. The second is to investigate and react upon cases where legal requirements may have been violated. NHBS oversees if health enterprises have management and governance systems that ensure a satisfying level of quality and safety in the transfusion services.

1.1. External audit and supervision

Quality and safety in health care may be promoted in different ways [4,5]. Initiatives may be internal and voluntary or forced upon service providers through legal requirements or external audits and inspections [6,7]. The terminology in the field is not uniform, and local terms may not always have a precise English translation. The Scandinavian word *tilsyn* refers to activities that one could translate into supervision, inspection, control, audit, etc., but no single English word fully captures its meaning. The use of the word *tilsyn* in Scandinavian languages, as well as the word *toesicht* in Dutch, is often related to governmental or other public regulatory activities. *Tilsyn* involves controlling adherence to legal requirements at the service provision level, as well as enforcement of corrective activities where legal requirements have not been met. We will use the English word *supervision* for characterizing the total set of activities related to control of provision of health services and possible subsequent instruction by governmental authorities. The word

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audit will be applied to the method or instrument used for performing the regulatory control.

1.2. Legal standards and the principle of "internal control"

Many legal requirements are written in general terms, such as the Norwegian legal requirement for "sound professional practice". In legal science these formulations are often named "legal standards". This concept may be compared to the concept of reasonable man standard known from Anglo-American tort law. Such legal standards have to be operationalized before they can be used as criteria or evaluating scale in an audit of a quality management system. A regulatory based audit thus requires a cross professional co-operation, involving legally trained staff as well as health personnel with relevant competence. Another core concept when performing audits of health services is the principle of "internal control", or regulated self-regulation [8]. This applies to legal norms that demand the service providers, on all managerial levels, to demonstrate in a systematic way that they by themselves have implemented and are continuously monitoring adherence to all relevant legal requirements as a part of their ordinary governance systems.

1.3. National audit and supervision of blood banks

Planned audit of transfusion services is a legal requirement, and in 2008 and 2009, all the 24 Norwegian health enterprises with blood banks were approached by NHBS. The aim of governmental supervision was to discover conditions deviating from accepted norms and legal requirements, and to support continuous organizational development. Requirements for the quality management system for internal control were communicated, and subsequently a nation-wide audit was performed by inspecting one blood bank in each health enterprise. Health enterprises are required to organize and deliver blood products according to legal regulations, and to ensure that clinical practice is according to "sound professional standards". Legal requirements have traditionally not specified outcomes, and the NHSB have thus focused on responsibilities, structures, and processes that are assumed to be relevant for securing desired outcomes. NHBS' supervisory activity was performed as an external audit, which here will be defined as a system-oriented inspection of structural aspects such as governing documents, including documentation of clinical procedures and how they are monitored. The findings from the supervisory activity were presented to the organization under supervision in a preliminary report. The organization was invited to comment on the preliminary report before a final report was sent to the enterprises and was also published on the web site of the NHSB. The supervisory authority followed up institutions where deviations have been demonstrated, until deviations were corrected in a sound manner.

1.4. Aim of the study

There is limited evidence of the effectiveness of external audits, inspection and supervision [5]. Little is known about the organizational impact of supervisory activities in blood banks, and there has recently been a call for increased use of qualitative methods in this field [9]. Inspired by theories on organizational learning which highlights how knowledge is created, retaining and shared within an organization [10,11], we had an interest in understanding more about the organizational effects following a governmental audit of blood transfusion services in Norway. How was the audit experienced by health professionals? What changes and activities took place within the organizations? In order to identify recommendations for future audits and supervisory work in health care, we did a study with the aim to explore health professional's experiences with the external audit of blood transfusion services in Norway.

2. Materials and methods

We considered a qualitative study, using focus groups to collect data [12], as a suitable method for exploring health professionals' experiences of the audit and supervision. We chose to conduct focus group interviews because we considered this as a feasible approach to gather data, and we also wanted to elicit experiences in the team at each of the three hospitals. We used a purposeful sampling strategy to recruit participants from three different health enterprises from different regions in Norway. In addition to geographic variation, we choose hospitals and blood banks of different sizes. We also chose units with different audit results.

2.1. Focus group interviews

We approached health professionals through a letter of invitation, and recruited a total of 18 participants, with 5–7 participants in each of the three focus groups. Group participants were the manager for the blood transfusion service, medical doctors, quality managers, and representatives for other groups working in the service. In two of the groups, higher level managers in the hospital participated. We developed an interview guide with open-ended questions, and among specific questions that were discussed were: How was the audit experienced? What did the health enterprises learned from their own and others' deviations? What barriers and facilitator to change existed? The first author moderated three focus group interviews in 2010. The interviews lasted roughly 60 minutes, and were digitally recorded.

2.2. Analysis

The audio-files were transcribed verbatim, and the material was subject to qualitative analysis, following the principles of systematic text condensation [13]: (i) reading all the material to obtain an overall impression and bracketing previous preconceptions; (ii) identifying units of meaning, representing different aspects of the theme and coding for these; (iii) condensing and summarizing the contents of each of the coded groups; and (iv) to generalize descriptions and concepts about the specific theme. The first author did a preliminary analysis, and the other authors joined in and participated in the final analysis.

Illustrating quotes have been translated from Norwegian by the authors. The translations have been done according to the principle of concordant translation (formal equivalent translation), where the aim is to maintain as great verbal and syntactic similarities between the original and the translated text as possible.

2.3. Ethics

The study was a built-in process evaluation of the nationwide audit of blood banks, and the study as such did not influence clinical activities. Data about individual patients or employees were not collected, and approval from ethical review board was not necessary. All participants were informed about the purpose of the study, and gave their written consent to participate in the interviews.

3. Results

3.1. Learning from other blood banks

The audit reports from other blood banks were published successively on the website of NBHS, and contained information about deviations. Participants told that they had used these reports to analyze their own activities and systems for internal control in order to implement necessary changes in their own blood banks before being audited:

"When the media coverage started we were following what happened. Thus we realized where we had deficiencies which we had to work with. […] We knew that our turn would come soon, so it was worthwhile trying to do something about it as soon as we could."

Managers and professionals thus learned indirectly about the legal requirements and professional standards, due to the publicity and reports from other organizations.

3.2. Creating awareness

Managers and health professionals experienced the audit and supervision as demanding, and extra time and efforts were needed to submit documents and correct subsequent deviations that were described in the preliminary report. Some professionals and managers reported having difficulties with understanding what the deviations and legal regulations in the reports meant in practice, especially those related to the requirements on a quality management system, but a general experience was that the audit resulted in increased awareness of quality issues and motivation to make changes:

"I do want to say that we have had audits before, but they were not so demanding, and they have not required that we evaluated ourselves as we were forced to now […] we really became aware that this time we had to think in a different way …"

The informants endorsed the audit's patient-centered focus and the focus on potential system deviations at higher organizational levels. The informants experienced that the audit had brought attention to system deficiencies and practices, and was a catalyst for quality improvement. Still, hospitals varied in their approach. While some organizations worked systematically to implement sustainable changes, others were more occupied with making changes to close deviations in order to terminate the audit and supervision.

3.3. Facilitators to change

Among facilitators to change health professionals reported managerial support, access to resources, expertise in quality improvement work, involvement of employees, and professional pride. One informant underlined:

"We want to show that we can do a good job. It actually meant something that we did not have any deviations […] We have a strong professional pride, and we do it well!"

The audit could marshal support from managers for quality improvements. One professional said:

"It even led to some issues coming up in the budget somewhat sooner than it might otherwise have done. Yes. The audit was a push to get it in place."

Managers at the department level told they had received feedback from employees who appreciated to know that the job they did was in accordance with approved standards.

3.4. Barriers to change

Some health professionals claimed that they could not prioritize working systematically with improving quality due to time constraints. Professionals in the blood banks requested more clarity about responsibilities for blood products, to ensure that products were managed and used correctly. Health professional in blood banks reported that they had difficulties gaining support for changes from other parts of the organization:

"And they did not think in the same way as I did, and it was very difficult, how shall I put it … to get a thorough understanding of how systems and structures should be built and connected […] we have always done it this way, and it has functioned well, so why should we do more?"

Blood bank managers argued that they lacked authority to make decisions about staff in clinical departments, and had difficulties with implementing desired changes across the organization:

"We do not have a system at the health enterprise today that ensures that what we discover and reports are being dealt with in a correct manner in the clinical departments. There may be incorrect transfusions and situations that could have caused incorrect transfusions. It is very dependent upon the persons involved and the culture. It tells me that the system does not work".

The audit revealed that the senior management in hospitals was involved to a various extent, and in some organizations blood bank personnel experienced a lack of support and understanding from management at superior levels in the hospital:

"I have experienced that we owned our local deviations and that the important thing was to write that we had corrected the deviation, irrespective of what we really had done".

In general, the blood banks struggled to get the necessary help from the senior management, even though both the audit and the following audit report were directed to the chief executive officer at the health enterprise. Some of the blood bank managers argued that some of the corrective actions undertaken had the character of "firefighting" due to lack of resources and lack of support from senior management.

4. Discussion

4.1. Main findings

We found that the audit and continuous publication of results created national awareness about legal standards and common deviations in blood banks. The audit and supervision was experienced as demanding, but brought attention to deficiencies in systems and practices, and had been a catalyst for quality improvement. Facilitators to change were managerial support, access to resources, expertise in quality improvement, involvement of employees, and professional pride. Lack of time, poor dialogue with clinical departments, unclear division of responsibilities for handling of blood products between the blood bank and the clinical departments, and lack of support from senior management were perceived as barriers to change.

4.2. Shared understanding of deviations and challenges

Being exposed to an external audit by a public authority is demanding and cumbersome for the inspected organizations. Therefore supervisory activities should be experienced as useful, not only seen from the regulator's perspective, but also from the viewpoint of the service providers. Our study suggests that professionals and senior managers struggled to understanding the content of the supervisory report and did not understand the real content of the legal requirements. Lack of shared understanding may create resistance to regulatory supervision. To increase the comprehension of the findings from the supervisory activity, on-site inspections and a concluding meeting with the involved managers should be included in every inspection. When carrying out audits based on documents, auditors should ensure a common understanding of the findings and the possible deviations. Using words and concepts that professionals are able to understand could facilitate understanding and organizational change.

4.3. Triggers for change

The audit and the subsequent report and supervisory activities seem to be an important trigger for change. Some organizations were aware about published reports from audits in other organizations and used them as a starting point for organizational development and improvement. Quite a lot of media presentations of the audits in the blood banks contributed to bring attention to the audit and is likely to have trigged responses inside the organizations as the leaders would like to avoid negative publicity about own organization. Being proud about own organization's professional competence also was reported as an important driver for improvement. The employees at the blood banks experienced that governmental supervision can act as a catalyst to initiate and complete changes which they previously have struggled to bring to the attention of the managers of the health enterprises. Governmental supervision intentionally should stimulate the enterprises' own work with quality improvement, and thus support necessary changes and improved patient safety. Our study suggests that input from outside, as from a supervisory organization, can create readiness for improvement and promote organizational learning. Some professionals claimed that they could not prioritize a systematic approach to quality improvement in a day characterized by busy routines, which may indicated that senior management allow for ad-hoc solutions or "firefighting", which might be preferable under some circumstances. Still, such an approach is a typical example single-loop learning [10] that may hinder deeper and more sustainable change. If so, one may questions if the organization's safety culture is not at a sufficient high level. It may also be interpreted as a signal that the organization accepts breaches of legal requirements or lacking routines ensuring that such requirements are followed in practice.

4.4. Involving senior management

The personnel at the blood banks experienced that they were made responsible for correcting the deviations. They received scarce support from senior management, such as Clinic Directors, which was problematic when other departments of the hospital were involved. Safety issues related to storage and handling of blood products has been highlighted previously [14]. In order to involve senior management, auditing and supervising organizations, such as the NBHS, need to address more specifically the relevant managerial level. Auditing organizations should investigate how managers supervise their own organization and ensure that implemented changes lead to necessary changes in clinical and laboratory practice, and that the changes sustain over a longer period of time. Special focus must be given to the intersection between different departments and clinics in order to enhance the organizational impact of audits and supervision. Audit reports should clearly address senior level responsibilities, and special consideration should be given to how senior management manages deviations, particularly when several departments in a hospital are involved.

The results have been used by NBHS in planning the next rounds of inspection of blood banks by emphasizing the control of managerial responsibilities, as the ability to clarify responsibilities is one effect of the system audit.

4.5. Methodological considerations

This is a qualitative study relying upon a small sample of three hospitals, but we think the data reflect variety in experiences and views that can give us further knowledge

on the supervisory process. The interviews were conducted by a researcher who was employed at the organization that was responsible for the audit. This ensures a thorough knowledge about this specific topic, but may have biased responses in the focus groups. Nonetheless, there was an open atmosphere in the groups and a willingness to share the negative experiences, and we claim that the internal validity of our study is good. Exploratory qualitative work aiming to get a better understanding of processes and administrative conditions cannot claim to give a broad picture of how the situation is in general. We think our study pinpoint some mechanisms and factors that can inform future policy and research. We think the results from this study may be transferable to blood bank activities in other health enterprises.

5. Conclusions

Governmental audit and supervision of blood banks may foster organizational development. Audits can bring attention to known deficiencies, and trigger improvement processes which previously have not been prioritized. In order to secure resources and to promote organizational learning and enduring change across departments, audits need to address and involve senior managers.

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